

2728, 53 Stat. 1424, 1425, provided for care and treatment of addicts.

Section 227, act Jan. 19, 1929, ch. 82, §7, 45 Stat. 1086, provided for transfer to and from farms of addicts who are prisoners.

Section 228, act Jan. 19, 1929, ch. 82, §8, 45 Stat. 1087, provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts.

Section 229, act Jan. 19, 1929, ch. 82, §9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for employment of addicts.

Section 230, act Jan. 19, 1929, ch. 82, §10, 45 Stat. 1087, provided for parole of inmates.

Section 231, act Jan. 19, 1929, ch. 82, §11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for discharge of addicts.

Section 232, act Jan. 19, 1929, ch. 82, §12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for admission of voluntary patients.

Section 233, act Jan. 19, 1929, ch. 82, §13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for furnishing of gratuities and transportation to discharged convicts.

Section 234, act Jan. 19, 1929, ch. 82, §14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided penalties for introduction of narcotic drugs into a narcotic farm.

Section 235, act Jan. 19, 1929, ch. 82, §15, 45 Stat. 1089, provided penalties for escape of inmates.

Section 236, act Jan. 19, 1929, ch. 82, §16, 45 Stat. 1089, provided penalties for procuring of escape by inmates.

Section 237, act Jan. 19, 1929, ch. 82, §17, 45 Stat. 1089, provided for deportation of alien inmates who are entitled to a discharge from narcotic farms.

#### RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered §711 by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049, §713 by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47, §813 by act July 30, 1956, ch. 779, §3(b), 70 Stat. 720, §913 by Pub. L. 88-581, §4(b), Sept. 4, 1964, 78 Stat. 919, §1013 by Pub. L. 89-239, §3(b), Oct. 6, 1965, 79 Stat. 931, §1113 by Pub. L. 91-572, §6(b), Dec. 24, 1970, 84 Stat. 1506, §1213 by Pub. L. 92-294, §3(b), May 16, 1972, 86 Stat. 137, §1313 by Pub. L. 93-154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, §7(b), Dec. 29, 1973, 87 Stat. 936.

### CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

#### SUBCHAPTER I—SHORT TITLE

Sec.  
301. Short title.

#### SUBCHAPTER II—DEFINITIONS

321. Definitions; generally.  
321a. "Butter" defined.  
321b. "Package" defined.  
321c. Nonfat dry milk; "milk" defined.  
321d. Market names for catfish and ginseng.

#### SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

331. Prohibited acts.  
332. Injunction proceedings.  
333. Penalties.  
333a. Repealed.  
334. Seizure.  
335. Hearing before report of criminal violation.  
335a. Debarment, temporary denial of approval, and suspension.  
335b. Civil penalties.  
335c. Authority to withdraw approval of abbreviated drug applications.  
336. Report of minor violations.

Sec.  
337. Proceedings in name of United States; provision as to subpoenas.

#### SUBCHAPTER IV—FOOD

341. Definitions and standards for food.  
342. Adulterated food.  
343. Misbranded food.  
343-1. National uniform nutrition labeling.  
343-2. Dietary supplement labeling exemptions.  
343-3. Disclosure.  
343a. Repealed.  
344. Emergency permit control.  
345. Regulations making exemptions.  
346. Tolerances for poisonous or deleterious substances in food; regulations.  
346a. Tolerances and exemptions for pesticide chemical residues.  
346b. Authorization of appropriations.  
347. Intrastate sales of colored oleomargarine.  
347a. Congressional declaration of policy regarding oleomargarine sales.  
347b. Contravention of State laws.  
348. Food additives.  
349. Bottled drinking water standards; publication in Federal Register.  
350. Vitamins and minerals.  
350a. Infant formulas.  
350b. New dietary ingredients.  
350c. Maintenance and inspection of records.  
350d. Registration of food facilities.  
350e. Sanitary transportation practices.  
350f. Reportable food registry.

#### SUBCHAPTER V—DRUGS AND DEVICES

##### PART A—DRUGS AND DEVICES

351. Adulterated drugs and devices.  
352. Misbranded drugs and devices.  
353. Exemptions and consideration for certain drugs, devices, and biological products.  
353a. Pharmacy compounding.  
353b. Prereview of television advertisements.  
354. Veterinary feed directive drugs.  
355. New drugs.  
355-1. Risk evaluation and mitigation strategies.  
355a. Pediatric studies of drugs.  
355b. Adverse-event reporting.  
355c. Research into pediatric uses for drugs and biological products.  
355d. Internal committee for review of pediatric plans, assessments, deferrals, and waivers.  
355e. Pharmaceutical security.  
356. Fast track products.  
356-1. Accelerated approval of priority countermeasures.  
356a. Manufacturing changes.  
356b. Reports of postmarketing studies.  
356c. Discontinuance of life saving product.  
357. Repealed.  
358. Authority to designate official names.  
359. Nonapplicability of subchapter to cosmetics.  
360. Registration of producers of drugs or devices.  
360a. Clinical trial guidance for antibiotic drugs.  
360b. New animal drugs.  
360c. Classification of devices intended for human use.  
360d. Performance standards.  
360e. Premarket approval.  
360e-1. Pediatric uses of devices.  
360f. Banned devices.  
360g. Judicial review.  
360h. Notification and other remedies.  
360i. Records and reports on devices.  
360j. General provisions respecting control of devices intended for human use.  
360k. State and local requirements respecting devices.  
360l. Postmarket surveillance.  
360m. Accredited persons.

|   |   |  |   |
|---|---|--|---|
| Sec.<br>360n.   | Priority review to encourage treatments for tropical diseases.                                      | Sec.<br>379a.<br>379b.   | Presumption of existence of jurisdiction.<br>Consolidated administrative and laboratory facility. |
| PART B—DRUGS FOR RARE DISEASES OR CONDITIONS            |   | 379c.  | Transferred.  |
| 360aa.  | Recommendations for investigations of drugs for rare diseases or conditions.                        | 379d.  | Automation of Food and Drug Administration.   |
| 360bb.  | Designation of drugs for rare diseases or conditions.   | 379d-1.  | Conflicts of interest.  |
| 360cc.  | Protection for drugs for rare diseases or conditions.   | 379d-2.  | Policy on the review and clearance of scientific articles published by FDA employees.             |
| 360dd.  | Open protocols for investigations of drugs for rare diseases or conditions.                         | PART B—COLORS  |   |
| 360ee.  | Grants and contracts for development of drugs for rare diseases and conditions.                     | 379e.  | Listing and certification of color additives for foods, drugs, devices, and cosmetics.            |
| PART C—ELECTRONIC PRODUCT RADIATION CONTROL             |   | PART C—FEES  |   |
| 360hh.  | Definitions.  | SUBPART 1—FREEDOM OF INFORMATION FEES  |   |
| 360ii.  | Program of control.   | 379f.  | Recovery and retention of fees for freedom of information requests.                               |
| 360jj.  | Studies by Secretary.   | SUBPART 2—FEES RELATING TO DRUGS   |   |
| 360kk.  | Performance standards for electronic products.  | 379g.  | Definitions.  |
| 360ll.  | Notification of defects in and repair or replacement of electronic products.                        | 379h.  | Authority to assess and use drug fees.  |
| 360mm.  | Imports.  | 379h-1.  | Fees relating to advisory review of prescription-drug television advertising.                     |
| 360nn.  | Inspection, records, and reports.   | 379h-2.  | Reauthorization; reporting requirements.  |
| 360oo.  | Prohibited acts.  | SUBPART 3—FEES RELATING TO DEVICES   |   |
| 360pp.  | Enforcement.  | 379i.  | Definitions.  |
| 360qq.  | Repealed.   | 379j.  | Authority to assess and use device fees.  |
| 360rr.  | Federal-State cooperation.  | 379j-1.  | Reauthorization; reporting requirements.  |
| 360ss.  | State standards.  | SUBPART 4—FEES RELATING TO ANIMAL DRUGS  |   |
| PART D—DISSEMINATION OF TREATMENT INFORMATION           |   | 379j-11.   | Definitions.  |
| 360aaa to 360aaa-6.                                     | Omitted   | 379j-12.   | Authority to assess and use animal drug fees.   |
| PART E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES |   | PART D—INFORMATION AND EDUCATION   |   |
| 360bbb.   | Expanded access to unapproved therapies and diagnostics.  | 379k.  | Information system.   |
| 360bbb-1.   | Dispute resolution.   | 379l.  | Education.  |
| 360bbb-2.   | Classification of products.   | PART E—ENVIRONMENTAL IMPACT REVIEW   |   |
| 360bbb-3.   | Authorization for medical products for use in emergencies.  | 379o.  | Environmental impact.   |
| 360bbb-4.   | Technical assistance.   | PART F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS |   |
| 360bbb-5.   | Critical Path Public-Private Partnerships.  | 379r.  | National uniformity for nonprescription drugs.  |
| 360bbb-6.   | Risk communication.   | 379s.  | Preemption for labeling or packaging of cosmetics.  |
| PART F—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES |   | PART G—SAFETY REPORTS  |   |
| 360ccc.   | Conditional approval of new animal drugs for minor use and minor species.                           | 379v.  | Safety report disclaimers.  |
| 360ccc-1.   | Index of legally marketed unapproved new animal drugs for minor species.                            | PART H—SERIOUS ADVERSE EVENT REPORTS   |   |
| 360ccc-2.   | Designated new animal drugs for minor use or minor species.   | 379aa.   | Serious adverse event reporting for nonprescription drugs.  |
| SUBCHAPTER VI—COSMETICS                                 |   | 379aa-1.   | Serious adverse event reporting for dietary supplements.  |
| 361.  | Adulterated cosmetics.  | PART I—REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION  |   |
| 362.  | Misbranded cosmetics.   | 379dd.   | Establishment and functions of the Foundation.  |
| 363.  | Regulations making exemptions.  | 379dd-1.   | Location of Foundation.   |
| 364.  | Repealed.   | 379dd-2.   | Activities of the Food and Drug Administration.   |
| SUBCHAPTER VII—GENERAL AUTHORITY                        |   | SUBCHAPTER VIII—IMPORTS AND EXPORTS  |   |
| PART A—GENERAL ADMINISTRATIVE PROVISIONS                |   | 381.   | Imports and exports.  |
| 371.  | Regulations and hearings.   | 382.   | Exports of certain unapproved products.   |
| 372.  | Examinations and investigations.  | 383.   | Office of International Relations.  |
| 372a.   | Transferred.  | 384.   | Importation of prescription drugs.  |
| 373.  | Records.  | SUBCHAPTER IX—MISCELLANEOUS  |   |
| 374.  | Inspection.   | 391.   | Separability clause.  |
| 374a.   | Inspections relating to food allergens.   |  |   |
| 375.  | Publicity.  |  |   |
| 376.  | Examination of sea food on request of packer; marking food with results; fees; penalties.           |  |   |
| 377.  | Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests. |  |   |
| 378.  | Advertising of foods.   |  |   |
| 379.  | Confidential information.   |  |   |

|       |  |
|-------|--|
| Sec.  |  |
| 392.  | Exemption of meats and meat food products. |
| 393.  | Food and Drug Administration.              |
| 393a. | Office of Pediatric Therapeutics.          |
| 394.  | Scientific review groups.                  |
| 395.  | Loan repayment program.                    |
| 396.  | Practice of medicine.                      |
| 397.  | Contracts for expert review.               |
| 398.  | Notices to States regarding imported food. |
| 399.  | Grants to States for inspections.          |
| 399a. | Office of the Chief Scientist.             |

## SUBCHAPTER I—SHORT TITLE

## § 301. Short title

This chapter may be cited as the Federal Food, Drug, and Cosmetic Act.

(June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

## EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, §§ 1, 2, 53 Stat. 853, 854, provided that:

“[SEC. 1] (a) The effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c) [342(c) of this title]; 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k) of this title]; 501(a), (4) [351(a)(4) of this title]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; 601(e) [361(e) of this title]; and 602(b) [362(b) of this title].

“(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940 the effective date of the provisions of sections 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k)]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; and 602(b) [362(b) of this title] of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

“SEC. 2. (a) The provisions of section 8 [section 10 of this title], paragraph fifth, under the heading ‘In the case of food’, of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 [section 10 of this title] and of such regulations, shall remain in force until January 1, 1940.

“(b) The provisions of such Act of June 30, 1906, as amended, [sections 1 to 5, 7 to 15, and 372a of this title] to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act [section 343(k) of this title], shall remain in force until January 1, 1940.

“(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

“(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act [352(d), (e) of this title], insofar as such provisions relate to any substance named in section 8 [section 10 of this title], paragraph second, under the heading ‘In the case of drugs’, of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

“(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act [352(b), (d) to (h) of this title], insofar as such provisions relate to drugs to which section 505 [355 of this title] of such Act applies.”

## EFFECTIVE DATE

Section 902(a) of act June 25, 1938, provided that: “This Act [enacting this chapter and repealing sections 1 to 5 and 7 to 15 of this title], shall take effect twelve months after the date of its enactment [June 25, 1938]. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 [section 371 of this title] shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) [section 343(i) of this title] for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401 [section 341 of this title]: *Provided further*, That sections 502(j), 505, and 601(a) [sections 352(j), 355, 361(a), respectively of this title], and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) [section 361(a) of this title], relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U.S.C., 1934 ed., title 21, sec. 6 [section 321a of this title]; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U.S.C., 1934 ed., title 21, sec. 10 [section 321b of this title]; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U.S.C. 1934 ed., Sup. III, title 21, sec. 14a [section 372a of this title]) shall remain in force and effect and be applicable to the provisions of this Act.”

## SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110–85, § 1, Sept. 27, 2007, 121 Stat. 823, provided that: “This Act [enacting part I of subchapter VII of this chapter, chapter 26 of this title, sections 350f, 353b, 355–1, 355d, 355e, 360a, 360e–1, 360n, 360bbb–5, 360bbb–6, 379d–1, 379d–2, 379h–1, 379h–2, 379j–1, and 399a of this title, and section 247d–5a of Title 42, The Public Health and Welfare, amending sections 321, 331, 333, 334, 352, 355, 355a, 355c, 360, 360e, 360i, 360j, 360l, 360m, 360ee, 374, 379g, 379h, 379i, 379j, 379j–11, 379l, 381, and 393a of this title and sections 247d–3b, 262, 282, 283, 283a–2, 283a–3, 284m, 285g–10, 288–6, and 290b of Title 42, enacting provisions set out as notes under this section and sections 331, 350f, 352, 355, 355a, 355c, 360j, 379g, 379h, 379h–2, 379i, and 2110 of this title and section 282 of Title 42, and amending provisions set out as notes under section 284m of Title 42] may be cited as the ‘Food and Drug Administration Amendments Act of 2007’.”

Pub. L. 110–85, title I, § 101(a), Sept. 27, 2007, 121 Stat. 825, provided that: “This title [enacting sections 379h–1 and 379h–2 of this title, amending sections 379g, 379h, and 379j–11 of this title, and enacting provisions set out as notes under sections 379g, 379h, and 379h–2 of this title] may be cited as the ‘Prescription Drug User Fee Amendments of 2007’.”

Pub. L. 110–85, title II, § 201(a), Sept. 27, 2007, 121 Stat. 842, provided that: “This title [enacting section 379j–1 of this title, amending sections 333, 360, 360i, 360m, 374, 379i, and 379j of this title, and enacting provisions set out as notes under section 379i of this title] may be cited as the ‘Medical Device User Fee Amendments of 2007’.”

Pub. L. 110–85, title III, § 301, Sept. 27, 2007, 121 Stat. 859, provided that: “This title [enacting section 360e–1